The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensu**re**

Board of Registration of Pharmacy
239 Causeway St., Suite 200, 2nd Floor
Boston, MA 02114
(800) 414-0168 (office) / (617) 973-0983 (fax)

Self-Inspection Form for Pharmacy License Renewal – To Be Completed Prior To Approval for Manager Change and within 30 days of a Relocation, Transfer of Ownership and within 30 days of opening of a New Pharmacy/Pharmacy Department

Pharmacy Name: _____ **Store Number**: _____

Address: _____

Telephone Number: _____**Fax Number**: _____

Pharmacy Controlled Substance Registration # and Expiration Date: _____

Pharmacy DEA # and Expiration Date: _____

Pharmacy Hours: Daily _____-_____ Saturday _____-_____ Sunday _____-_____

Pharmacist Roster	**Name**	**License #**	**Exp. Date**
Pharmacist in Charge			
Staff Pharmacist			
Staff Pharmacist			
Staff Pharmacist			
Staff Pharmacist			

Computer Software Name _____
Helpdesk Phone Number _____

Supplier Information - including the supplier name and toll free number of controlled substances
1) Name: _____ Phone: _____

2) Name: _____ Phone: _____
3) Name: _____ Phone: _____
INSTRUCTIONS: Place a Check Next to Those in Compliance ***ONLY***

1. Display Requirements:

a. The pharmacy permit [247CMR 6.02(3)(a)]	
b. The pharmacy's Massachusetts controlled substance registration [247 CMR 6.02(3)(b)]	
c. The pharmacy's U.S. Drug Enforcement Administration controlled substance registration [247 CMR 6.02(3)(c)]	
d. Whenever applicable, the pharmacy certificate of fitness [247 CMR 6.02(3)(d)]	
e. The name of the pharmacist Manager of Record located at the main entrance of the pharmacy or pharmacy department on a sign that is not less than one inch high [247 CMR 6.02(7)]	
f. A reasonably sized sign affixed to the main entrance of the business in an easily observable area identifying the presence of a pharmacy of pharmacy department [247 CMR 6.02(5)]	
g. The hours of operation at all consumer entrances to the pharmacy and in the case of a pharmacy department, hours shall also be posted at consumer entrances to the retail store and at the pharmacy department [247 CMR 6.02(8)(a)]	
h. A sign of not less than 11 inches in height and 14 inches in width informing customers of their rights to counseling by a pharmacist. Said sign shall be placed at each area where prescriptions are dispensed including drive-through windows. Said sign shall read: "Dear patients: You have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist." [247 CMR 9.07(3)]	
i. Name tags and job title shall be worn by personnel including job title [247 CMR 8.01(11), 247 CMR 8.02((3)(a) and 247 CMR 8.04 (2)(a)]	
j. Each full time pharmacist's certificate of registration to practice pharmacy and the original or copy of the current wallet registration card [247 CMR 6.02(9)(b)]	

COMMENTS AND CORRECTIVE MEASURES:_____
_____
_
_____
_
_____
_
_____

2. The following references are to be maintained on the pharmacy premises:

a. A current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List, and the latest supplements thereto [247 CMR 6.01(5)(a)1]

b. A current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record [247 CMR 6.01(5)(a)2]

c. A current copy or electronic version of Board Regulations, 247 CMR 1.00 through 15.00 [247 CMR 6.01(5)(a)3]

COMMENTS AND CORRECTIVE MEASURES:_____

_____

_

_____

_

_____

_

_____

_

3. Equipment and Floor Design/Security Requirements:

a. A balance capable of accurately weighing quantities as small as 13 milligrams, which has been tested and sealed annually by the state or local sealer of weights and measures [247 CMR 6.01(5)(a)4]

b. The equipment necessary to conduct the practice of pharmacy according to the standards set forth by the most current edition of the United States Pharmacopoeia [247 CMR 6.01(5)(a)5]

c. Appropriate sanitary appliances, including a sink equipped with hot and cold running water located near the area where prescriptions are filled [247 CMR 6.01(5)(a)7]

d. An area of not less than 300 square feet allowing for pharmacy equipment and supplies and the facilitation of proper preparation and compounding of prescriptions [247 CMR 6.01(5)(b)]

e. A separate working alarm is in place for the pharmacy or pharmacy department which is activated when the pharmacy or pharmacy department is closed [247 CMR 6.02(6)(d)]

f. A floor to ceiling barrier is in place that secures the pharmacy department. This barrier is alarmed and locked when the pharmacy department is closed [247 CMR 6.02(6)(e)]

COMMENTS AND CORRECTIVE MEASURES:_____

_____

_

_____

4. Central Intravenous Admixture Service (CIVAS) Requirements:

a. In addition to the 300 square feet, as required by 247 CMR 6.01(5)(b), the clean room has a minimum working area of 72 square feet [247 CMR 6.01(5)(c)1]
b. The clean room is directly adjacent to the prescription area/department for those applications of construction that were received after September 30, 1996 [247 CMR 6.01(5)(c)(7)]
c. The room is closed on all sides except for a door and opening to allow for material passage [247 CMR 6.01(5)(c)2]
d. The room has a laminar flow hood with either vertical or horizontal flow that is certified annually to meet the standards of operation of HEPA (High Energy Particulate Air) filters and pre-filters [247 CMR 6.01(5)(c)(3)(4)]
e. The area of the clean room is under continual positive pressure unless the hood is self-venting [247 CMR 6.01(5)(c)(6)]
f. Date of last certification _____
g. By Whom _____

** All CIVAS Pharmacies should obtain a copy of Board Policy 96.003 "USP Guidelines for Clean Room Construction"

COMMENTS AND CORRECTIVE MEASURES:_____
_____
_
_____
_
_____
_
_____
_

5. Controlled Drug Prescriptions and Records Requirements

a. All controlled substances in Schedules II through IV are stored within the prescription area in a securely locked cabinet or dispersed throughout the Schedule VI controlled substances in a manner that obstructs theft or diversion of these substances [247 CMR 6.02(6)(a)(c)]
b. Controlled substances in Schedule VI are stored within the prescription area or in the clean room if the clean room is directly adjacent to the prescription area [247 CMR 6.02(6)(b)]
c. All drug order deliveries containing controlled substances are directly delivered to the pharmacy/ pharmacy department or to a secured area if the pharmacy is closed [247 CMR 6.02(6)(g)]
d. An inventory of controlled substances in Schedule II, III, IV and V is taken, based upon federal biennial inventory requirements, which the pharmacist Manager of Record signs and forwards to the board upon commencement and termination of employment [247 CMR 6.07(1)(i)]
e. Procedures are in practice for validating questionable purported controlled substance prescriptions to deter the willful and unlawful dispensing of controlled substances [247 CMR 6.07(1)(j)]

f. A perpetual inventory is kept by a pharmacist of each controlled substance in Schedule II that the pharmacist has received, dispensed or disposed. This inventory is reconciled at least once every 10 days [247 CMR 9.01(14)]

g. DEA 222 forms are compliant with the Code of Federal Regulations 21 CFR 1305.09(e). The blue copy includes the date and quantity of packages received. *Each* line must be filled out completely. Invoices should be readily retrievable.

h. The power of attorney, authorizing an individual to sign a DEA 222 form, present within the pharmacy.

i. A report is transmitted to the Department of Public Health or its agent containing the following information about Schedule II controlled substances dispensed: the prescription number, the patient identifier, pharmacy NABP number, date the controlled substance was dispensed, quantity dispensed, NDC number of the controlled substance dispensed, estimated days supply and the prescriber's DEA number. The report is transmitted no later than 15 days following the last day of the preceding month in which the prescription was dispensed [247 CMR 5.04]

COMMENTS AND CORRECTIVE MEASURES:_____

_____

_

_____

_

_____

_

_____

_

_____

6. Prescription Files Maintenance Requirements:

a. Prescriptions for controlled substances in Schedule II are segregated from all other records and maintained in a separate file identified as such [247 CMR 9.05(1)]

b. Prescriptions for controlled substances in Schedules III, IV and V and maintained in a separate file identified as such [247 CMR 9.05(2)]

c. Prescriptions for Schedule VI Controlled Substances, prescriptions for non-controlled substances and prescriptions for syringes and instruments adaptable to hypodermic administration are segregated from all other records and maintained together in a file identified as such [247 CMR 9.05(3)]

COMMENTS AND CORRECTIVE MEASURES:_____

_____

_

_____

_

_____

_

_____

_

_____

7. Electronically Transmitted Prescription Requirements:

a. Prescriptions or drug orders may be electronically transmitted from an authorized prescribing practitioner or his or her expressly authorized agent to a pharmacy or pharmacy department of the patient's choice. The prescription or drug order shall be electronically transmitted in a manner that maintains patient confidentiality and in accordance with the requirements of M.G.L. c. 94C, § 23(g) and 105 CMR 721.000 *et seq* [247 CMR 5.02(1)]

b. A pharmacist or pharmacy shall not enter into any agreement concerning the provision of a computer, facsimile machine, computer modem or any other electronic device which would adversely affect a patient's freedom to select the pharmacy or pharmacy department of his or her choice [247 CMR 5.02(2)]

c. A pharmacist or pharmacy shall not provide a computer, facsimile machine, computer modem or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer patients to a particular pharmacy or pharmacy department [247 CMR 5.02(3)]

d. A prescription for a non-emergency Schedule II controlled substance may be prepared in advance, however, before dispensing the original signed prescription must be presented to the pharmacist and compared to the prepared prescription before being released to the patient, except for long term care, home infusion or certified hospice settings

COMMENTS AND CORRECTIVE MEASURES:_____
_____
_
_____
_
_____
_
_____

8. Orally or Electronically Transmitted Schedule II Controlled Substances for Emergency Dispensing:

a. The prescription is marked "Authorization for Emergency Dispensing" [247 CMR 5.03(3)]

b. The pharmacist verifies that the Schedule II controlled substance quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period [247 CMR 5.03(2)(a)]

c. A written prescription is postmarked to the pharmacy within seven days after authorization. Upon receipt of the written prescription, the dispensing pharmacist shall attach the prescription to the orally or electronically transmitted emergency prescription which had been reduced to writing

COMMENTS AND CORRECTIVE MEASURES:_____
_____
_
_____
_
_____

_
_____
_
_____

9. Transferring Prescriptions Requirements:

a. Transfers of Schedules III, IV and V controlled substances are done on a one-time basis [247 CMR 9.02(4)]
b. The transferring pharmacist of a Schedule III, IV or V controlled substance writes the words "VOID" on the face of the invalidated prescription and the name, address and DEA number of the pharmacy being transferred to as well as the name of the pharmacist receiving the prescription information on the reverse side [247 CMR 9.02(2)(a)1-2] All refills remaining on the transferred prescription are canceled [247 CMR 9.02(2)(b)].
c. A record, either written or computerized, with the prescription number, date of transfer and name of pharmacist and pharmacy is kept for all Schedule III through VI controlled substances {247 CMR 9.02(2)(a)3 and 3(a)]
d. The transferred prescription information includes the date of issuance, original number of refills, date of original dispensing, number of valid refills remaining and last refill, the pharmacy's name, address, DEA number and prescription number and the name of the transferor pharmacist [247 CMR 9.02(2)(c)2]

COMMENTS AND CORRECTIVE MEASURES:_____
_____
_
_____
_
_____

10. Patient Records, Counseling and Prospective Drug Utilization Review:

a. A pharmacist or pharmacist designee obtains and maintains a confidential record for all patients for whom prescriptions are dispensed including the name, address, telephone number, date of birth or age and gender of patient, the patients history including known allergies and drug reactions and a comprehensive list of medications, the pharmacist's comments relevant to the patient's drug therapy [247 CMR 9.07(1)(a)]
b. A prospective drug utilization review (DUR) is conducted by the pharmacist before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient [247 CMR 9.07(2)(a)]
c. A pharmacist or pharmacist designee offers the services of the pharmacist to all persons presenting new prescriptions for filling [247 CMR 9.07(3)(a)]
d. Counseling is made by a pharmacist, or a pharmacy intern under the direct supervision of the pharmacist [247 CMR 9.07(3)(f)]
e. A record is maintained of the offer to counsel in either a signature log or electronic profile indicating that counseling was offered and received or offered and refused. (Note: The absence of any record to accept the pharmacist's offer to counsel assumes that counseling took place.)

- Are monographs used when dispensing : new prescriptions YES___ NO_____
- : refill prescriptions YES___ NO_____
- INTERACTION SOFTWARE SHOULD BE UPDATED QUARTERLY

COMMENTS AND CORRECTIVE MEASURES:_____
_____
_
_____
_
_____

11. Code of Professional Conduct:

a. The pharmacist Manager of Record is responsible for the establishment, monitoring and enforcement of policies and procedures that encourage and maintain the standards of professional practice [247 CMR 6.07(1)(d-e)]	
b. The pharmacist Manager of Record maintains adequate staff in the pharmacy in order to ensure that the practice of pharmacy be carried out in accordance with Board regulations [247 CMR 6.07(1)(f)]	
c. The pharmacist Manager of Record is responsible for records of current pharmacy technicians duties delegated to pharmacy technicians and the scope of responsibility of the pharmacy technician [274 CMR 8.02(6)]	
d. The pharmacist Manager of Record and the pharmacist on duty are responsible for pharmacy security and control access to the pharmacy area [247 CMR 6.02(6)(f)]	
e. The pharmacist has a corresponding responsibility to ensure that prescriptions are dispensed by a practitioner for a legitimate use in the usual course of professional practice [MGL c. 94C: section 19(a)]	

COMMENTS AND CORRECTIVE MEASURES:_____
_____
_
_____
_
_____

Certification:

I, _____, Manager of Record, R.Ph., do certify that I have completed the self-inspection of this pharmacy of which I am the pharmacist in charge. I certify that the information provided is true and accurate and subject to verification by the Board of Registration in Pharmacy. I have evaluated the pharmacy operations at this site, as indicated in this report, and shall initiate the appropriate measures in order to achieve compliance.

Signature: _____Date: _____

DO NOT MAIL COMPLETED SELF-INSPECTION FORM

Upon completion, retain this form with your Schedule II perpetual inventory.